



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-1459]

#### Generic Drug User Fee Amendments; Public Meeting; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of the Generic Drug User Fee Amendments (GDUFA) for fiscal years (FYs) 2023 through 2027. GDUFA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to assess and collect fees to support human generic drug activities. The current legislative authority for GDUFA expires at the end of September 2022. At that time, new legislation will be required for FDA to continue to assess and collect generic drug user fees for future fiscal years. The FD&C Act directs FDA, following negotiations with the regulated industry and periodic consultations with other stakeholders, to present recommendations for reauthorization of the GDUFA program to the relevant Congressional committees, publish the recommendations in the *Federal Register*, provide for a period of 30 days for the public to provide written comments on such recommendations, and hold a meeting at which the public may present its views on such recommendations. FDA will then consider such public views and comments and revise such recommendations as necessary.

**DATES:** The public meeting will be held on November 16, 2021, from 9 a.m. to 2 p.m. Eastern Time and will be held virtually. Submit either electronic or written comments on this public meeting by December 12, 2021. See the SUPPLEMENTARY INFORMATION section for registration date and information.

**ADDRESSES:** Registration to attend the virtual meeting and other information can be found at <https://www.eventbrite.com/o/fda-34063199905>. See the SUPPLEMENTARY INFORMATION section for registration date and information.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 12, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 12, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2020-N-1459 for “Generic Drug User Fee Amendments; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240-402-8926, [Dat.Doan@fda.hhs.gov](mailto:Dat.Doan@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of GDUFA, which authorizes FDA to assess and collect user fees to support human generic drug activities, which are defined under the FD&C Act<sup>1</sup> to include the activities necessary for the review (also called “assessment”) of generic human drug applications and Type II active pharmaceutical ingredient (API) drug master files (DMFs),<sup>2</sup> and for conducting inspections related to generic drugs, and to engage in other related activities. The current authorization of the program (GDUFA II) expires at the end of September 2022. Without new legislation, FDA will no longer be able to assess and collect user fees to help fund human generic drug activities for future fiscal years.

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<sup>1</sup> See section 744A(9) of the FD&C Act (21 U.S.C. 379j-41(9)).

<sup>2</sup> Type II active pharmaceutical ingredient drug master file means a submission of information to the Secretary by a person that intends to authorize FDA to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant. Section 744A(13) of the FD&C Act.

Section 744C(f)(4) of the FD&C Act (21 U.S.C. 379j-43(f)(4)) requires that after FDA negotiates with the regulated industry,<sup>3</sup> we do the following: (1) present recommendations for reauthorization of the GDUFA program to the relevant Congressional committees, (2) publish such recommendations in the *Federal Register*, (3) provide for a period of 30 days for the public to provide written comments on such recommendations, (4) hold a meeting at which the public may present its views on such recommendations, and (5) after consideration of such public views and comments, revise such recommendations as necessary.

This notice, the 30-day comment period, and the public meeting described in this notice will satisfy certain of these statutory requirements. After the public meeting, we will revise the recommendations as necessary and present the proposed recommendations to the appropriate Congressional committees.

The purpose of the public meeting announced in this *Federal Register* notice is to obtain the public's views on the proposed recommendations for the reauthorized program (GDUFA III). The following information is provided to help potential meeting participants better understand the history and evolution of the GDUFA program and the proposed GDUFA III recommendations.

## II. What is GDUFA and What Does It Do?

GDUFA amended the FD&C Act to authorize FDA to assess and collect fees from drug companies that submit marketing applications for human generic drug applications, as well as from certain DMFs holders and from manufacturing facilities referenced in generic drug applications. GDUFA was originally enacted in 2012 as part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) and was authorized for a period of 5 years.

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<sup>3</sup> Section 744C(f)(3) of the FD&C Act requires periodic consultation with representatives of patient and consumer advocacy groups during negotiations with the generic drug industry.

In 2017, the GDUFA user fee program was reauthorized under the FDA Reauthorization Act of 2017 (Pub. L. 115-52, Title III), for FYs 2018 through 2022 (GDUFA II). GDUFA II was designed to finance critical and measurable generic drug program enhancements intended to help speed public access to safe, effective, and high-quality generic drugs. As described in the GDUFA II Commitment Letter, FDA committed to achieve certain performance goals, provide enhanced communication intended to streamline abbreviated new drug application (ANDA) development and assessment, and take other steps to increase the efficiency of the assessment process. GDUFA II's Commitment Letter also established a pre-ANDA program to make transparent FDA's regulatory expectations for complex generic product developers early in product development and during application assessment.

Additional information concerning GDUFA, including the text of the law, the GDUFA II Commitment Letter, key *Federal Register* documents, and GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at <https://www.fda.gov/gdufa>.

### III. Proposed GDUFA III Recommendations

In preparing the proposed recommendations to Congress for GDUFA reauthorization for GDUFA III, FDA conducted discussions with the regulated industry and consulted with patient and consumer advocacy groups, as required by the law, among other stakeholders. FDA began the GDUFA reauthorization process by publishing a notice in the *Federal Register* requesting public input on the reauthorization and announcing a public meeting, which was held on July 21, 2020 (85 FR 38378, June 26, 2020). The meeting included presentations by FDA and different stakeholder groups, including patient and consumer advocacy groups, regulated industry, health professionals, and academic researchers. The materials from the meeting, including the agenda, presentations, and transcript can be found at <https://www.fda.gov/drugs/public-meeting-reauthorization-generic-drug-user-fee-amendments-gdufa-07212020-07212020>. The stakeholders were asked to respond to the following questions:

- What is your assessment of the overall performance of the GDUFA program to date?
- What aspects of GDUFA should be retained, changed, or discontinued to further strengthen and improve the program?
- What new features should FDA consider adding to the program to enhance efficiency and effectiveness of the generic drug review process?

Following the July 2020 public meeting, FDA conducted negotiations with the regulated industry and continued monthly consultations with other stakeholders from September 2020 through August 2021. As directed by Congress, FDA posted minutes of these meetings on its website: <https://www.fda.gov/drugs/development-approval-process-drugs/gdufa-iii>. The proposed enhancements for GDUFA III address many of the top priorities identified by FDA, the regulated industry, and other stakeholders. These include proposed program enhancements to advance approvals in fewer review cycles, proposals to enhance regulatory science and expedite complex generic drug development, and financial proposals to support the generic drug program as it evolves. The full descriptions of these proposed recommendations can be found in the proposed GDUFA III Commitment Letter (Proposed Commitment Letter), which will be posted prior to the public meeting on FDA's website at [www.fda.gov/gdufa](http://www.fda.gov/gdufa).

The enhancements are described below with references to the section of the Proposed Commitment Letter where more detailed information can be found.

#### *A. Advancing Approvals*

The enhancements made in GDUFA II were successful in increasing the number of generic drug approvals throughout its implementation. The proposed GDUFA III commitments are intended to build on this success to reduce the number of review cycles needed for approval by maximizing the value of each cycle and increasing the number of first-cycle approvals.

*ANDA Assessment Efficiencies*--FDA proposes several changes to the assessment process to increase communication and efficiency. For example, FDA proposes to work with industry to resolve minor issues during the review cycle, even when this may require goal date extensions,

and to minimize complete response letters (CRLs) in which the only deficiency is labeling. In addition, FDA proposes to expand opportunities for timely regulatory advice through the expansion of the definition of controlled correspondence used in the Commitment Letter and, for certain applications, the opportunity for a post-CRL scientific meeting. FDA also proposes to utilize “imminent actions” when it may be possible to approve an application within 60 days after the goal date in certain circumstances. More examples can be found in the Proposed Commitment Letter, section II.

*Drug Master Files (DMFs)*--FDA proposes several enhancements related to the review of DMFs, including the opportunity for holders of certain DMFs to submit a request for assessment of the DMF 6 months prior to the planned submission date for certain original ANDAs, amendments containing a response to a CRL, and amendments seeking approval of an ANDA that previously received a tentative approval. In addition, FDA proposes to implement procedures to enhance the efficiency of the review of DMF amendments related to original ANDAs and prior approval supplements. Details of these enhancements can be found in the Proposed Commitment Letter, section VI.

*Pre-Submission Facility Correspondence (PFC)*--The PFC process was established for GDUFA II to reduce the review goal date to 8 months for ANDA submissions that qualify for priority review per MAPP 5240.3, Prioritization of the Review of Original ANDAs, Amendments, and Supplements<sup>4</sup>. For GDUFA III, FDA proposes to refine the description of the manufacturing information to be submitted in a PFC to focus on the information that is needed to inform FDA’s decision regarding the need for a preapproval inspection. In addition, FDA proposes to reduce the information regarding bioequivalence and clinical studies needed in a PFC to focus on the key information needed by FDA to determine the need for a preapproval inspection and to better align with the timing of development programs. Details of the PFC enhancements can be found in the Proposed Commitment Letter, section II.F.

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<sup>4</sup> Available at: <https://www.fda.gov/media/89061/download>.

*Facility Assessments*--Although GDUFA II has generally been successful, facility assessments continue to be an area of opportunity for program improvement. For example, FDA recognizes that a manufacturing facility's violative compliance status may be resolved between the issuance of a CRL that included facility inspection-related deficiencies and the time of the applicant's CRL response. Where the resolution of the compliance status also resolves the facility-related deficiencies identified in a CRL, FDA proposes that applicants have the opportunity to request reclassification of facility-based Major CRL amendments to Minor amendments, thereby expediting the assessment of the submitted amendment. Details of the reclassification enhancement can be found in the Proposed Commitment Letter, section II.C.7.

To help resolve facility inspection deficiencies, FDA proposes to establish Post-Warning-Letter Meetings for eligible facilities to obtain preliminary feedback from FDA on the adequacy and completeness of the facility's corrective action plans. FDA further proposes to improve clarity regarding the generic drug manufacturing facility reinspection process with goal dates and metrics. Details of these facility enhancements and more can be found in the Proposed Commitment Letter, section VII.

#### *B. Pre-ANDA Program*

The goals of the pre-ANDA program are to establish transparent regulatory expectations for prospective applicants early in product development, assist applicants in developing complete submissions, promote a more efficient and effective ANDA assessment process, and reduce the number of assessment cycles required to obtain ANDA approval. The pre-ANDA program has been especially useful and successful in fulfilling these goals for complex generic products, and the proposals for GDUFA III are intended to expand on this success. Full details of the pre-ANDA program can be found in the Proposed Commitment Letter, section III.

*Suitability Petitions*--FDA proposes to work to enhance the Agency's processes for the review of new and pending suitability petitions. Under the proposal, beginning in FY 2024, suitability petitions would be assigned goal dates and prioritized based on parameters, such as

public health emergency, mitigating possible pharmaceutical waste, or for products under the President's Emergency Plan for AIDS Relief. Details of the proposed suitability petition enhancements can be found in the Proposed Commitment Letter, section III.B.

*Product-Specific Guidance (PSG)*--Under GDUFA II, FDA established goals around PSGs for new chemical entities in order to facilitate generic competition. In GDUFA III, FDA proposes new goals around PSGs for complex products to further aid in the development of generic versions of complex drug products. FDA proposes to provide on its website information related to upcoming new and revised PSGs. FDA would make the prioritization of PSG development publicly available and allow for industry and public input on prioritization.

In addition, recognizing that regulatory science continually evolves, FDA proposes that qualified ANDA applicants or potential applicants may request a PSG Teleconference to obtain Agency feedback on the potential impact of new recommendation(s) on ongoing bioequivalence studies. Details of the proposed PSG program enhancements can be found in the Proposed Commitment Letter, section III.C.

### *C. ANDA Assessment Meeting Program*

The goal of the ANDA Assessment Meeting Program is to provide targeted, robust advice to ANDA applicants as they work to meet the requirements for ANDA approval. FDA proposes two significant enhancements starting with the Enhanced Mid-Cycle Review Meeting, which would allow applicants to inquire about new data or information to address any possible deficiencies identified in a Discipline Review Letter. FDA also proposes the addition of a post-CRL Scientific Meeting in which the Agency may provide a qualified applicant scientific advice on possible alternative approaches to address deficiencies identified in a CRL related to establishing sameness. Details on the proposed ANDA Assessment Meeting Program enhancements can be found in the Proposed Commitment Letter, section IV.

### *D. Continued Enhancement of User Fee Resource Management*

FDA is committed to ensuring the sustainability of GDUFA program resources and to enhancing the operational agility of the GDUFA program through maturation of the Resource Capacity Planning (RCP) capability and the proposed implementation of a Capacity Planning Adjustment (CPA). The CPA would allow for increases in inflation-adjusted target revenue for the upcoming fiscal year as a result of expected workload increases for certain human generic drug activities. Specifically, FDA proposes an amendment to the statute to add authority for the implementation of a CPA, which also would bring the GDUFA program in alignment in this respect with the Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Amendments (BSUFA) programs. Under the proposed agreement, the CPA would be implemented starting in fiscal year 2024 and would include certain limits on its authorized increases. Continued maturation of RCP would include areas such as (1) continual improvement of time reporting to support enhanced management of GDUFA resources and (2) the integration of RCP analyses in the Agency's resource and operational decision-making processes.

In addition, new statutory language is proposed for GDUFA III to provide a mechanism to manage financial risks by authorizing a minimum amount of available operating reserves to be maintained each year. As proposed for GDUFA III, the amount of operating reserves that can be added through additional fees would be no more than 8 weeks of operations in FY 2024, increasing to a maximum of 10 weeks of operations by FY 2026. In addition, if operating reserves are estimated to exceed 12 weeks, there would be a reduction in fees to maintain the operating reserve at no more than 12 weeks.

FDA and industry also proposed the following changes to the allocation of total fee revenues among fee categories: (1) the proportion of fee revenues derived from API facility fees would decrease from 7 percent in GDUFA II to 6 percent in GDUFA III; (2) the fee revenues derived from generic drug facility fees (also referred to as finished dosage form or FDF fees) would remain at 20 percent, but the fee for contract manufacturing organizations would decrease from one-third of the annual FDF fee in GDUFA II to 24 percent of the annual FDF fee in

GDUFA III; and (3) the proportion of fee revenues derived from the generic drug applicant program fee would increase from 35 percent in GDUFA II to 36 percent in GDUFA III.

*E. Impact of GDUFA III Enhancements on User Fee Revenue*

To implement the proposed enhancements for GDUFA III, funding for a total of 128 new full-time equivalent staff is proposed for FY 2023.

IV. Public Meeting Information

*A. Purpose and Scope of the Meeting*

The meeting will include presentations by FDA and panels representing different stakeholder groups identified in the statute (such as patient and consumer advocacy groups and regulated industry). For members of the public who would like to make verbal comments on the proposed enhancements (see instructions below), there will be a public comment period at the end of the meeting. We will also provide an opportunity for individuals to submit written comments to the docket before and after the meeting.

*B. Participating in the Public Meeting*

*Registration:* Registration is optional to attend this virtual meeting. However, registering will allow FDA to provide you with email updates if any meeting details change. Persons interested in registering for this public meeting must register online by 11:59 p.m. Eastern Time on November 15, 2021, at <https://www.eventbrite.com/o/fda-34063199905>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

*Opportunity for Public Comment:* If you wish to present during the public comment session, please submit your request to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov) by 11:59 p.m. Eastern Time on November 8, 2021. Your email should contain which topic(s) you wish to address and include complete contact information, including name, title, affiliation, address, and email address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their

presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by November 9, 2021. If selected for presentation, any presentation materials must be emailed to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov) no later than November 11, 2021. No commercial or promotional material will be permitted to be presented or distributed during the virtual public meeting.

*Streaming Webcast of the Public Meeting:* The Zoom Webinar ID for this public meeting is 160 003 0426. The webcast link for this public meeting, which should allow you to enter the webinar directly, can be found here:

<https://fda.zoomgov.com/j/1600030426?pwd=YThMd0sweXNQOVNOdVpYZHMrdVFSUT09>.

If Zoom asks for a passcode, please use the following case-sensitive passcode: GDUFa3!

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments> and in this docket at <https://www.regulations.gov>. It may also be viewed at the Dockets Management Staff (see ADDRESSES).

Dated: October 22, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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